DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-478/S-010

Abbott Laboratories
Hospital Products Division
D-389, Bldg. AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-6157

Attention: Mike Sliwoski, M.S.
Associate Director, Regulatory Affairs

Dear Mr. Sliwoski:

Please refer to your supplemental new drug application dated May 23, 2001, received May 29, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ultane (Abbott).

This supplemental new drug application provides final printed labeling (package insert) that includes text describing hepatic changes associated with sevoflurane use and deletion of the sentence pertaining to the reported death associated with seizures.

We have completed the review of this supplemental application and it is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Lisa Basham, Regulatory Project Manager, at (301) 827-7420.

Sincerely,

Cynthia McCormick, M.D.
Director
Division of Anesthetic, Critical Care, and
Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research